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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,411	09/28/2006	Martin T. Lowy	PB60808	8514

20462 7590 06/18/2009
SMITHKLINE BEECHAM CORPORATION
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EXAMINER

CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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06/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/599,411	Applicant(s) LOWY, MARTIN T.	
	Examiner KATHRIEN CRUZ	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants response filed March 18, 2009 has been received and entered in the application.

Priority

This application claims priority of PCT/US05/10125 (dated 03/25/2005) which claims benefit of provisional application 60/556,391 (dated 03/25/2004).

Action Summary

Claim 1 is rejected under 35 U.S.C. 112, first paragraph is withdrawn in view of the cancellation of the claim.

Claims 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Emonds-Alt et al (U.S. Publication 6, 420, 388) is withdrawn.

Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emonds-Alt et al (U.S. Publication 6, 420, 388) as applied to claims 5 and 8 above, and further in view of Guttuso, JR (U.S. Publication 2002/0016283) is maintained.

Response to Arguments

Applicants argue that Emonds-Alt does not disclose the use of talnetant would be useful for treating bipolar disorder. This argument has been fully considered but has not been found persuasive. Emonds-Alt teaches the use of an NK3 antagonist to treat

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bipolar disorder (claims 1 and 7). While it is true that Emonds-Alt does not expressly disclose talnetant as the NK3 antagonist, Talnetant is a well-known NK3 antagonist according to Guttuses. It is obvious that since it is known that NK3 antagonist are useful in the treatment of bipolar disorder as taught by Emonds-Alt, employing any known NK3 antagonists, including talnetant, would be reasonably expected to be useful in the treatment of bipolar disorders. Therefore, the limitations of Claim 5, 7 and 8 set forth has been met.

Applicants are respectively reminded that arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, taking the teachings of the prior art as a whole, the claims are properly rejected under 35 USC 103(a).

For the ease of the applicant, the office action dated December 26, 2008 has been reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5, 7 and 8 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Emonds-Alt et al (U.S. Publication 6, 420, 388) as applied to claims 5 and 8 above, and further in view of Guttuso, JR (U.S. Publication 2002/0016283) both are of record.

Applicant claims a method for preventing or treating bipolar disorder by administering an effective amount of NK₃, specifically talnetant.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Emonds-Alt et al teaches that antagonist of the human NK₃ receptor which are useful for the treatment of disorder associated with dysfunction of the dopaminergic and noradrenergic systems (column 1, lines 28-31). Emonds-Alt et al teaches a method of treatment of bipolar disorders with the administration of osanetant (which is a NK₃ antagonist) (claims 1 and 7).

Guttuso teaches talnetant hydrochloride is an NK₃ receptor antagonist (paragraph 0038). Guttuso teaches that talnetant may be used as an inhalation (paragraph 0028).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant application and Emonds-Alt et al is that Emonds-Alt does not teach the specifically disclose talnetant as the NK₃ antagonist or the method of administration is in the form of “free base”. This deficiency in Emonds-Alt is cured by the teachings of Guttuso.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Emonds-Alt because talnetant is an NK₃ receptor antagonist as taught by Guttuso.

One of ordinary skill in the art would have been motivated to do this because the administration of NK₃ receptor antagonist is known for the effective treatment of bipolar disorders.

With regards to talnetant in the form of free base, this would encompass administration of talnetant by means of inhalation which would be routine by one skilled in the art.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Claims 5, 7 and 8 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617